K023546

BIOMET

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SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 17 2003

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(574) 267-6639

Device(s): Maxim Accel Knee System

Classification Name: Cemented semi-constrained polymer/metal/polymer (888.3560)

Device Classification: Class II

Device Product Code: 87 JWH

Substantially Equivalent Devices: MCK (K915132); Performance (K936274)

Device Description: The Maxim Accel Knee System is intended to replace the articular portions of the knee joint. The system consists of three femoral components with augmentation pieces and three modular tibial bearings.

Indications for Use:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The device is a single use implant intended for implantation with bone cement.

Summary of Technologies: The femoral component and tibial bearings have been redesigned. The Maxim Accel Knee System is similar to or identical in terms of function, labeling, and sizing to the predicate MCK device(s).

Non-Clinical Testing: The Maxim Accel Knee System is intended to replace the articular portions of the knee joint. The system consists of three femoral components with augmentation pieces and three modular tibial bearings. All mechanical testing was done in accordance to 1994-*Draft guidance for the preparation of Premarket Notifications (510(j)s) for cemented, semi-constrained total knee prostheses.*

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Ms. Tracy Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K023546
Trade/Device Name: Maxim Accel Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 18, 2002
Received: October 22, 2002

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023546
Device Name: **Maxim Accel Knee System**
Indications for Use:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

The device is a single use implant intended for implantation with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023546 MNM
K023546